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07/508840

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KUBEL, P EXAMINER

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ART UNIT	PAPER NUMBER
332 332	6 03/05/91

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> _____ |

Part II SUMMARY OF ACTION

1. ☒ Claims 4, 6, 10-15, 17, 18, 20, 21, 23-26 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 4, 6, 10-15, 17, 18, 20, 21, 23-26 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received
☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as incomplete.

Applicant in his specification calls for a method and apparatus for preventing the formation of the Herpes Simplex Lesion and the disruption of the Herpes Simplex 1 and 2 virus attack. Applicant states his invention manipulates the "electric state of the cell so as to assist the cell in fighting off a viral attack."

The results, described in Table 1.1, do not adequately support the conclusions -noted in the specification page 19.

The clinical studies contain procedural errors. The group selection did not depend on the subject's disease stage. The subject's disease stage was not identical. The disease stage ranged from 1.5 to 5 years. The selection of groups, without considering disease onset, could skew results. The procedure assumes lesion development to be identical for each subject. A random group selection may not be adequate given the small number

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of subjects. The applicant states the DC current prevents growth of the "Herpes Virus by simulating the cell capacitance to return the cell to normal functioning." The specification does not provide verification of this statement or the apparatus's biological mechanism for prevention.

Diethelm's apparatus provides a means for accelerating the healing of Herpes Simplex -"within two days of treatment the condition of the skin will have improved i.e the secreting areas will dry up and local therapy will no longer be necessary" {page 4,line 51}. The apparatus involves using pulsed DC current. Diethelm's biological mechanism could be similar to the applicants, since both devices use DC current applied to the inflicted area.

Claims 4,6,10-15,17,18,20,21,23-26 rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 4,6,10-15,17,18,20,21,23-26 are rejected under 35 U.S.C. § 101 because of reasons advanced above.


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Any inquiry concerning this communication should be directed to Mr. P. Kubel at telephone number (703) 308-0858.


Vincent Millin
Primary Examiner



Mr. P. Kubel
February 20, 1991

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